Remarks

Claims 2, 3, 5, 6, 8, 9, 11, 12, 14, 15, 17, 18, 22, 24-27, 31, 32, 39, 41 to 43, 45, and 47 to 63 have been canceled without prejudice or disclaimer. New claims 64-131 have been added. Support for new claims 64-131 may be found throughout the specification as originally filed, including for example, at paragraphs [0016]-[0017], [0039], [0139], [0237], [0241]-[0245], [0249] and [0272]-[0278]. Accordingly, no new matter has been entered.

Claims 1 and 7 have been amended to correct typographical errors. Claim 1 has been amended so as to properly identify an amino acid sequence of TR13 as being disclosed in SEQ ID NO:2. Claim 7 has been amended so as to properly identify SEQ ID NO:39 as encoding the amino acid sequence of TR13 as disclosed in SEQ ID NO:40. As these amendments serve to correct obvious typographical errors, no new matter has been entered.

Claims 1, 4, 7, 10, 13, 16, 19-21, 23, 28-30, 33-38, 40, 44, 46 and 64-131 will be pending upon entry of this amendment. No new matter has been added by way of amendment.

Restriction Requirement

The Examiner has required an election of the claimed subject matter under 35 U.S.C. § 121 of one of the following groups:

A. Claims 1-33, drawn to polynucleotides, vectors, host cells and recombinant method of producing protein, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3 and 69.1, for example.
B. Claims 40-43, drawn to polypeptides, classified in class 530, subclass 350, for example.
C. Claims 44 and 45, in so far as they are drawn to antibodies, classified in class 530, subclass 388.22, for example.

D. Claims 46, 47, 52, 53, 59, 60 and 63, in so far as they are drawn to a method of treatment comprising administering a polypeptide of Group II, classified in class 514, subclass 2, for example.
E. Claims 46-63, drawn to a method of treatment comprising administering an agonist to the polypeptide of Group B, classified in class 514, subclass 2, for example.
F. Claims 46-63, drawn to a method of treatment comprising administering an antagonist to the polypeptide of Group B, classified in class 514, subclass 2, for example.
G. Claim 74 and 87-92, in so far as they are drawn to gene therapy, classified in class 514, subclass 44.

See, Paper No. 5, page 2. The Examiner contends that the inventions are distinct, each from the other.

In order to be fully responsive, Applicants hereby provisionally elect, *with traverse*, the invention of Group A as defined by the Examiner to include original claims 1-33 and newly added claims 64-131, in so far as they are drawn to nucleic acid molecules encoding a TR13 polypeptide. Applicants reserve the right to file one or more divisional applications directed to non-elected subject matter should the restriction requirement be made final. In such case, Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

Applicants respectfully traverse and request the withdrawal of the Restriction Requirement. As a threshold matter, Applicants point out that MPEP § 803 lists the criteria for a proper restriction requirement:

> Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 – § 806.04(i)) or distinct (MPEP § 806.05 – § 806.05(i)).
> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

See, M.P.E.P. § 803 at 800-[3-4]. Thus, even assuming, *arguendo*, that the seven (7) groups listed by the Examiner represented distinct or independent inventions, restriction remains improper unless it can be shown that the search and examination of multiple groups would entail a "serious burden." *Id.* In the present situation, no such showing has been made.

Preliminarily, Applicants point out that Group G as defined by the Examiner encompasses claims 74 and 87 to 92, which were not pending in the instant application prior to entry of the present amendment. Furthermore, the Examiner has classified Groups D, E and F in the same class and subclass (class 514, subclass 2) indicating that they have not acquired a separate status in the art, and therefore they would not present a serious burden to search and examine together.

Thus, in view of M.P.E.P. § 803, the claims of all of Groups A-F should be searched and examined in the subject application. Applicants submit that a search of the sequence of Group A would provide useful information for the sequences of the other Groups. Indeed, since the different groups are directed to portions of the same sequences (SEQ ID NOs:1, 4, 39 and 60), a search of each of the groups would largely, if not entirely, overlap. Thus, since the searches for sequence of group A, polypeptides of group B, antibodies of group C and methods of treatment of groups D, E and F would overlap, the search and examination of all these groups would not entail a serious burden.

Further Restriction Within Groups A-G.

The Examiner has required further restriction of the claimed subject matter within Groups A-G. In order to be fully responsive, Applicants hereby provisionally elect, *with traverse*, within the invention of Group A as defined by the Examiner, a TR13 nucleic acid of SEQ ID NO:39 encoding a polypeptide of SEQ ID NO:40. Applicants reserve the right

to file one or more divisional applications directed to non-elected subject matter should the restriction requirement be made final. In such case, Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

Applicants respectfully point out that the Examiner has not disclosed any statutory or regulatory basis for the further restriction within the provisionally elected group A. The Examiner alleges that "[t]he claims are drawn to numerous patentably distinct nucleic acid sequences, each of which constitutes a patentably distinct product." *See*, Paper No. 5, page 6. Applicants note that the Examiner is requiring an election of group members of the Markush-type claims. Applicants respectfully point out that MPEP § 803.02 requires that "[i]f the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits." Applicants submit that the members of the Markush groups of the pending claims to provisionally elected group A are sufficiently few in number and very closely related, as they are all different ***portions of the same polynucleotide sequences***, so that a search of all of the members may be made without a serious burden, contrary to the Examiner's position. Moreover, even assuming that examination of the entire claim would present a serious burden, MPEP § 803.02 states that "[f]ollowing election, the Markush-type claim will be examined fully as to the elected species and further to the extent necessary to determine patentability." If no prior art is found "that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended." *Id.* (emphasis added).

Further, Applicants point out that the Examiner has not addressed MPEP § 803.04, directed to nucleotide sequences. Pursuant to the notice *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996), §803.04 holds that even when nucleotide sequences encoding different proteins are

contained in an application, a reasonable number, normally ten sequences, will be examined in a single application. Applicants submit that the instant nucleic acids encode ***different fragments of the same proteins***, rather than different proteins as contemplated by § 803.04. Section 803.04 further states that "nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together." Thus, Applicants respectfully submit that the present requirement for further election within groups A-G is improper. However, even if the Examiner contends that the instant nucleic acids encode different proteins within the scope of §803.04, Applicants submit that a reasonable number of such nucleic acids should be examined together, and the Examiner has given no indication why ten sequences are unreasonable in the present case.

Accordingly, Applicants respectfully request that the Restriction Requirement Under 35 U.S.C. § 121 and the further restriction within groups A-G be withdrawn and the instant claims be examined in one application.

Identification of claims corresponding to the elected invention

The Examiner has required the identification of claims corresponding to the elected invention. *See*, Paper No. 5, page 7. In order to be fully responsive Applicants indicate that the provisionally elected invention of the present application is claimed in pending claims 1(o)-1(x), 4, 7, 10, 13, 16, 19-21, 23, 28-30, 33-38, and 64-131.

Applicants respectfully point out that the Examiner has not disclosed any statutory or regulatory basis for requirement to identify claims corresponding to the provisionally elected invention. Accordingly, Applicants respectfully point out that this requirement is improper and should be withdrawn.

In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance. An early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Dated: February 10, 2003

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KKH/LJH/BM
Enclosures

VIA HAND DELIVERY FEBRUARY 10TH, 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: YOUNG et al.

Application Serial No.: 10/046,433 Art Unit: 1646

Filed: January 16, 2002 Examiner: O'Hara, E.

For: Human Tumor Necrosis Factor Receptors TR13 and TR14 Attorney Docket No.: **PF511P1**

Version With Markings Showing Changes Made

In the Claims:

Claims 2, 3, 5, 6, 8, 9, 11, 12, 14, 15, 17, 18, 22, 24-27, 31, 32, 39, 41 to 43, 45, and 47 to 63 have been canceled without prejudice or disclaimer.

Claims 1, 7 and 33 have been replaced by the following amended claims:

--1. (Once Amended) An isolated nucleic acid molecule comprising a polynucleotide having a nucleotide sequence at least 95% identical to a sequence selected from the group consisting of:

(a) a nucleotide sequence encoding a polypeptide comprising amino acids from about 1 to about 750 in SEQ ID NO:~~1~~2;

(b) a nucleotide sequence encoding a polypeptide comprising amino acids from about 1 to about 750 in SEQ ID NO:~~1~~2;

(c) a nucleotide sequence encoding a polypeptide comprising amino acids from about 1 to about 750 in SEQ ID NO:~~1~~2;

(d) a nucleotide sequence encoding a polypeptide having the amino acid sequence encoded by the cDNA clone contained in ATCC Deposit No. PTA-349;

(e) a nucleotide sequence encoding the mature TR13 polypeptide having the amino acid sequence encoded by the cDNA clone contained in ATCC Deposit No. PTA-349;

(f) a nucleotide sequence encoding a polypeptide comprising amino acids from about 1 to about 231 in SEQ ID NO:61;

(g) a nucleotide sequence encoding a polypeptide comprising amino acids from about 2 to about 231 in SEQ ID NO:61;

(h) a nucleotide sequence encoding a polypeptide comprising amino acids from about 1 to about 138 in SEQ ID NO:61;

(i) a nucleotide sequence encoding a polypeptide having the amino acid sequence encoded by the cDNA clone contained in ATCC Deposit No. PTA-348;

(j) a nucleotide sequence encoding a polypeptide comprising amino acids 1 to 226 of SEQ ID NO:5;

(k) a nucleotide sequence encoding the TR14 extracellular domain;

(l) a nucleotide sequence encoding the TR14 transmembrane domain;

(m) a nucleotide sequence encoding the TR14 intracellular domain;

(n) a nucleotide sequence encoding the TR14 receptor extracellular and intracellular domains with all or part of the transmembrane domain deleted;

(o) a nucleotide sequence encoding a polypeptide comprising amino acids from about 1 to about 1001 in SEQ ID NO:40;

(p) a nucleotide sequence encoding a polypeptide comprising amino acids from about 2 to about 1001 in SEQ ID NO:40;

(q) a nucleotide sequence encoding a polypeptide comprising amino acids from about 42 to about 1001 in SEQ ID NO:40;

(r) a nucleotide sequence encoding a polypeptide having the amino acid sequence encoded by the cDNA clone contained in ATCC Deposit No. PTA-507;

(s) a nucleotide sequence encoding the mature TR13 polypeptide having the amino acid sequence encoded by the cDNA clone contained in ATCC Deposit No. PTA-507;

(t) a nucleotide sequence encoding the TR13 extracellular domain;

(u) a nucleotide sequence encoding the TR13 transmembrane domain;

(v) a nucleotide sequence encoding the TR13 intracellular domain;

(w) a nucleotide sequence encoding the TR13 receptor extracellular and intracellular domains with all or part of the transmembrane domain deleted; and

(x) a nucleotide sequence complementary to any of the nucleotide sequences in (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (p), (q), (r), (s), (t), (u), (v), or (w).

7. (Once Amended) The nucleic acid molecule of claim 1, wherein said polynucleotide has the nucleotide sequence in SEQ ID NO:39 encoding the TR~~1~~413 receptor having the amino acid sequence in SEQ ID NO:40.

33. (Once Amended) ~~An~~The isolated nucleic acid molecule of claim 1 comprising a polynucleotide having a sequence at least 95% identical to a sequence selected from the group consisting of:

(a) the nucleotide sequence of clone HETAQ12R (SEQ ID NO:48);
(b) the nucleotide sequence of clone HETAK82R (SEQ ID NO:49);
(c) the nucleotide sequence of clone HETBM71R (SEQ ID NO:50);
(d) the nucleotide sequence of clone HETBH18R (SEQ ID NO:51);
(e) the nucleotide sequence of clone HEPAB26R (SEQ ID NO:52);
(f) the nucleotide sequence of clone HETAN38R (SEQ ID NO:53);
(g) the nucleotide sequence of clone HPWDD30R (SEQ ID NO:54);
(h) the nucleotide sequence of clone HETAT05R (SEQ ID NO:55);
(i) the nucleotide sequence of clone HETDQ39R (SEQ ID NO:56);
(j) the nucleotide sequence of clone HPWBL93R (SEQ ID NO:57);
(k) the nucleotide sequence of clone HETEM84R (SEQ ID NO:58);
(l) the nucleotide sequence of clone HSIDV42R (SEQ ID NO:59); and
(m) a nucleotide sequence complementary to any of the nucleotide sequences in (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l) or (m) above.--

New claims 64-131 have been added.